

A research methodology study to map the process of initiating and operating a randomised controlled trial of podoconiosis treatment in Northern Ethiopia

Article (Published Version)

Lang, Trudie, Clarke, Mike, Newport, Melanie J, Enquoselassie, Fikre, van Loggerenberg, Francois, Franzen, Sam, Furtado, Tamzin, Njuguna, Patricia, Fegan, Greg and Davey, Gail (2013) A research methodology study to map the process of initiating and operating a randomised controlled trial of podoconiosis treatment in Northern Ethiopia. *Trials*, 14 (Suppl1). O31. ISSN 1745-6215

This version is available from Sussex Research Online: <http://sro.sussex.ac.uk/id/eprint/53012/>

This document is made available in accordance with publisher policies and may differ from the published version or from the version of record. If you wish to cite this item you are advised to consult the publisher's version. Please see the URL above for details on accessing the published version.

Copyright and reuse:

Sussex Research Online is a digital repository of the research output of the University.

Copyright and all moral rights to the version of the paper presented here belong to the individual author(s) and/or other copyright owners. To the extent reasonable and practicable, the material made available in SRO has been checked for eligibility before being made available.

Copies of full text items generally can be reproduced, displayed or performed and given to third parties in any format or medium for personal research or study, educational, or not-for-profit purposes without prior permission or charge, provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

ORAL PRESENTATION

Open Access

A research methodology study to map the process of initiating and operating a randomised controlled trial of podoconiosis treatment in Northern Ethiopia

Trudie Lang^{1*}, Mike Clarke², Melanie Newport³, Fikre Enquoselassie⁵, Francois van Loggerenberg¹, Sam Franzen¹, Tamzin Furtado¹, Patricia Njuguna⁴, Greg Fegan⁴, Gail Davey⁶

From 2nd Clinical Trials Methodology Conference: Methodology Matters
Edinburgh, UK. 18-19 November 2013

There is global inequity in medical research both in terms of populations who do not have access to the best evidence-led health care and in medical and scientific staff taking part in research studies. Alongside this is international recognition that trials have become overly cumbersome in their operation and regulation and that they are too expensive. There is widespread agreement that there needs to be changes in the way trials are designed and operated in order to make them more pragmatic and thereby attractive and viable for researchers (and their funders). A common complaint is the lack of published examples and best practices in operational approaches in running clinical trials. Here we report our on-going research methodology study that follows the steps and processes that are involved in setting up a highly pragmatic randomised clinical trial in Ethiopia and create a process map to report how the study was initiated and then subsequently operates. The primary object of this study is to determine all the issues and challenges that the trial team faces. Secondary objectives include an analysis of the study metrics, experience data from the study personnel and whether any lessons or solutions can either be shared or turned into a tool that others can benefit from for future studies.

Authors' details

¹University of Oxford, Oxford, UK. ²Queens University, Belfast, UK. ³Brighton and Sussex Medical School, Brighton, UK. ⁴Kemri-Wellcome Programme, Kilifi, Kenya. ⁵School of Public Health, Addis Ababa, Ethiopia. ⁶University of Sussex, Brighton, UK.

Published: 29 November 2013

doi:10.1186/1745-6215-14-S1-O31

Cite this article as: Lang et al.: A research methodology study to map the process of initiating and operating a randomised controlled trial of podoconiosis treatment in Northern Ethiopia. *Trials* 2013 **14**(Suppl 1):O31.

Submit your next manuscript to BioMed Central and take full advantage of:

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at
www.biomedcentral.com/submit



¹University of Oxford, Oxford, UK
Full list of author information is available at the end of the article